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EUROPEAN PATENT APPLICATION

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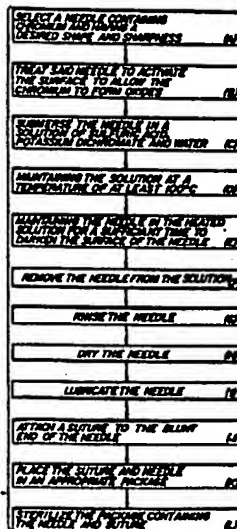
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⑤⑤ Designated Contracting States: **DE FR GB IT SE**

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⑤⑥ Sterile surgical needle having dark non-reflective surface.

⑤⑦ A sterile surgical needle having a dark, non-reflective and non-flaking surface. The needle is produced by selecting an appropriately shaped needle having the desired degree of sharpness. The needle is treated to activate the surface and then immersed in a solution of sulfuric acid, potassium dichromate and water to form a dark, non-reflective, non-flaking surface. The needle is sterilized to produce a sterile surgical needle of improved visibility.



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STERILE SURGICAL NEEDLE HAVING DARK NON-REFLECTIVE
SURFACE

5 The present invention relates to sterile surgical needles,
and more particularly to such needles which have a
uniformly dark and non-reflective surface.

BACKGROUND OF THE PRESENT INVENTION

10 In the past, sterile surgical needles generally have had a
bright or shiny chromium or silver type of surface. It
was thought this shiny surface, which was a result of
polishing for the most part, was required in order to
15 obtain desired sharpness and cutting characteristics or
penetration characteristics with the needle. A drawback
to these shiny surfaces is the difficulty they present in
being observed by the surgeon during a surgical procedure.
Cardiovascular surgeons and micro-surgeons have found it
quite difficult to use needles which reflect light in
20 surgery because of the reduced visibility of such needles.
With the advent of micro-surgery there is a similar
problem in lack of visibility within the surgical site of
these highly reflective needles.

25 Methods of blackening the reflective surfaces of metal
materials have been known for sometime and have been
attempted with surgical needles. To the best of my knowl-
edge, no one has been able to develop a suitably dull,
non-reflective needle as these blackening processes suffer
30 from one or more disadvantages. Often these blackening
processes form a coating on the needle which may flake
off during use. In some instances the processes form a
non-uniform non-reflective surface which causes visibility

problems as well as interfering with the sharpness characteristics of the needle. In most of these blackening processes the needle becomes dull as a result of the blackening treatment.

5

What I have discovered is a new method for blackening surgical needles and a new method for producing sterile surgical needles having a dark and non-reflective surface. The surface of my new needles do not flake and my new
10 needles have excellent sharpness and penetration characteristics. Other objects and advantages of the present invention will become readily apparent from a reading of the following detailed description and drawings.

15 SUMMARY OF THE PRESENT INVENTION

In accordance with the present invention, my new sterile surgical needle has a uniformly dark and non-reflective surface. The surface is non-flaking and the needle has
20 penetration characteristics substantially the same as needles having shiny and polished surfaces. The penetration characteristics of the needles of the present invention are less than 40 grams per mil of needle diameter to cause the needle to penetrate a given material and a
25 penetration factor of less than 1.5 grams per mil of needle diameter to cause the needle to pass through the material. The preferred needles of the present invention have a matte black surface. The method of the present invention for producing my new needles is to first select
30 a needle containing chromium. The needle should have the desired shape or configuration and degree of sharpness. The surface of the selected needle is treated such as by electrical processes to activate the surface by eliminating chromium rich oxides. The treated needle is submersed
35 in a solution of sulfuric acid, potassium dichromate, and water at a temperature in excess of 100°C. The needle is

maintained in the bath for a sufficient period of time to uniformly darken the surface of the needle and render that surface non-reflective. The needle is removed from the bath and may be rinsed with running hot water, ultrasonically rinsed at room temperature, air dried, lubricated and oven dried. It is preferred that the needles be lubricated with silicone and dried. The needle is sterilized by various well known sterilization techniques such as gas sterilization, irradiation, or the like. In most instances, a suture will be attached to the blunt end of the needle and the needle placed in a suitable package prior to sterilization.

BRIEF DESCRIPTION OF THE DRAWINGS

15

Figure 1 is a prespective view of one shape of needle of the present invention;

20

Figure 2 is a cross-sectional view taken along line 2-2 of Figure 1; and

Figure 3 is a box flow sheet showing the various steps in the method of the present invention.

25

DETAILED DESCRIPTION OF THE INVENTION

30

Referring to the drawings, in Figure 1 there is shown one shape of needle of the present invention. In this figure there is shown a curved needle. As shown in Figure 2 the cross-sectional shape of the needle, at least of the pointed end, is circular. The blunt end of the needle may have a suture attached thereto and in many instances the sides of the needle will be flattened to assist in grasping of the needle by a suitable needle holding instrument. The entire surface of the needle is dark and non-reflective and the surface is uniformly dark and non-

35

reflective. The surface is also non-flaking and the needle has excellent penetration characteristics. In the preferred embodiments of the needles of the present invention, the needle has a matte black finish. The
5 needles of the present invention may be made from any of the various steels containing chromium. The preferred materials are 300 or 400 series stainless steels.

To determine the characteristics of the needle surface,
10 the needles are tested for flaking characteristics. The tenacity and the non-flaking characteristics of the surface are evaluated by grasping the needle with a serrated jawed needle holder such as a Codman Classic Plus needle holder. The needle holder is closed to the first
15 locking position and released. The needle is examined under a scanning electron microscope at a magnification of approximately 500 times to determine whether any of the material has flaked. Also, the needles are examined at a magnification of 20 times to determine the intensity of
20 the color, the edge quality and the uniformity of the colored needle. The blackened needles are passed through a chamois under a microscope to see if any of the surface of the coating comes off on the chamois. The penetration performance of the needle is determined utilizing a curved
25 needle penetration tester. Two sensations are determined when testing the needle for penetration. The first is, the force to initially penetrate the point through a standard material and the second is to determine the drag on a needle as it passes through the appropriate material.
30 The combination of these forces is reflected in the total force to penetrate and is measured on an Instron tester.

Figure 3 is a block flow diagram depicting the various steps which may be used to produce the needles of the
35 present invention. First and as shown in Box A, the needle having the desired shape and a desired degree of

sharpness and made from a steel containing chromium is select d. The selected needle is treated (Box B) to render the surface of the needle activated; that is, to allow the chromium on the surface of the needle to form oxides. Two preferred techniques for activating the surface of the needle are to either electroclean or electropolish the needle immediately before the blackening treatment. If the surface of the needle is not suitably activated, a thin layer of the metal is removed in the process and the cutting edges dulled and the surface roughened or channeled. The dulling and roughening greatly increases the penetration forces required with the needle and make the needle unsuitable for use in many surgical procedures where tissue trauma must be kept to a minimum. The treated needle is submersed in a solution of sulfuric acid, potassium dichromate, and water (Box C). Solutions having a specific gravity of about 1.5 to 1.6 have been found satisfactory. The solutions contain from about 60 to about 65 percent by weight of sulfuric acid and from about 7 to about 10 percent of potassium chromate with the remainder being water. The solution is heated to a temperature of at least 100°C. and maintained above 100°C and below the boiling point of the solution or about 135°C (Box D). The needle is maintained in the solution for a sufficient length of time to darken the needle surface (Box E). Periods of time of from about 4 minutes up to 30 minutes or even longer have been found satisfactory. Other dichromate salts, such as sodium dichromate may also be used.

The needle is removed from the solution (Box F) and the needle rinsed to remove solution residue by running hot water over the needle (Box G). The needle is preferably ultrasonically rinsed and then dried in an oven or air-dried as desired (Box H). The needle is lubricated (Box I) and an appropriate suture is attached to the blunt end

of the needle (Box J). The blunt end of the needle would usually have a drilled hole or a channel with a suture swaged into the hole or channel as is well known in the art. The needle and suture is packaged in a suitable package (Box K) and the package sterilized (Box L) by cobalt radiation or ethylene oxide or other sterilization techniques as are well known in the art.

The invention will be more fully described by the following specific examples.

EXAMPLE I

A solution is prepared utilizing 180 mililiters of sulfuric acid, 50 grams of potassium dichromate and 200 mililiters of water. The solution has a specific gravity of from 1.52 to 1.55 and is maintained at a temperature of about 120° to 130°C. A curved needle having a round cross section and made from 45500 stainless steel is electropolished by immersing the needle in a suitable polishing acid and passing a current through the needle using the needle as an anode for from 4 to 60 seconds or more. The polished needle is immersed in the solution for from about 4 to 15 minutes. The needle is removed from the hot solution and rinsed ultrasonically with water. The needle is air dried, lubricated, oven dried and the dry needle examined and tested. The needle is examined under a scanning electron microscope by grasping the needle with a serrated jawed needle holder. The needle has a good matte black surface which is non-reflective and when examined under the electron scanning microscope no flaking of the black surface is detected.

The needle is tested for penetration characteristics by placing the needle in a rotating arm and pushing the needle through the penetration media following the arc of

the needle. A load cell measures the force on the penetration media as the needle passes through. The data is recorded on an X-Y recorder. The needle is 10 mils in diameter and the penetration results are for initial
5 penetration a force of 40 grams and for the drag on the needle as it passes through the media 18 grams.

EXAMPLE II

10 Similar needles are treated in the same bath. Needles are treated maintaining the bath at a temperature of 120°C. Needles which have had their surfaces treated with electropolishing and untreated needles are placed in the bath for from 5 to 30 minutes. In some cases, the needle
15 has some blackening on the surface but it is not uniform and in other cases the black surface which, though it may be uniform, is shiny and reflective.

EXAMPLE III

20 A needle which has not been treated to activate the surface is placed in the bath described in Example I while the bath is maintained at a temperature of 120° to 130°C. The needle is maintained in the bath for about 15 minutes.
25 The resulting needle has a matte black surface; however, 1/10 to 2/10 of the thickness of the surface is removed and the geometry of the cutting edges are altered and the tapered point is blunted. The needle is unsuitable as a surgical needle.

30

EXAMPLE IV

Needles as described in conjunction with Example I are placed in an oxidizing bath. The solution used is an
35 alkaline, oxidizing type, black oxidizing compound sold by Ethone, Inc. a subsidiary of ASARCO under the tradename

Ebanol SS.52. The bath is maintained at a temperature of about 121° to 126°C. Some of the needles are pre-treated by electropolishing to activate the needle surface. In all instances, the untreated or pre-treated needles have a uniform black surface. In some instances it is a shiny black surface. When these needles are tested for flaking the blackened surface readily flakes and the needles are unsuitable for surgical use.

10 EXAMPLE V

Needles as described in conjunction with Example I are treated utilizing a molten salt bath of sodium dichromate. The molten bath is maintained at a temperature of 875°F. and the needles are placed in the bath for about 30 to 45 minutes. The resultant needles are tested for surface characteristics under a scanning electro microscope. The surface has been considerably roughened and penetration studies show considerable increases in the force to penetrate. The resulting needles are not suitable for surgical use. Though the process might be optimized to produce acceptable needles the hazards associated with this process render it unsuitable for desired commercial manufacture.

25

Having now described the invention, it should be readily apparent that many variations and modifications may be made without departing from the spirit and scope of the present invention.

WHAT IS CLAIMED IS:

1. A sterile, surgical needle having a uniformly dark and non-reflective surface, said surface being non-flaking and said needle having penetration characteristics substantially the same as needles having shiny and polished surfaces.
2. A sterile, surgical needle according to Claim 1 having a penetration factor of less than 40 grams per mil of needle diameter to penetrate and 1.5 grams per mil of needle diameter to pass through material.
3. A sterile, surgical needle according to Claim 1 or 2 having a matte black surface.
4. A method of manufacturing sterile surgical needles having uniform dark and non-reflective surfaces, said surfaces being non-flaking, said method comprising:
 - (a) selecting a needle containing chromium, said needle having a desired configuration and sharpness,
 - (b) treating the surface of said needle to activate the needle surface to allow the chromium to form oxides,
 - (c) submersing said treated needle in a solution of sulfuric acid, potassium di chromate, and water,
 - (d) maintaining the temperature of the solution in excess of 100°C. while the needle is submersed,
 - (e) maintaining the needle in said heated solution for a sufficient length of time to uniformly darken the surface whereby said surface is non-reflective,

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(f) removing the needle from the bath and

(g) sterilizing the needle.

- 5 5. The method according to Claim 4 wherein the needle removed from the bath is rinsed with water, dried and lubricated.
- 10 6. The method according to Claim 4 wherein the treatment comprises either electro cleaning or electro polishing the needle.
- 15 7. The method according to Claim 4 wherein the solution is maintained at a temperature of from 110°C. to 130°C.
- 20 8. A method according to Claim 7 wherein the needle is maintained in the solution for a period of time from 4 to 15 minutes.
- 25 9. A method according to Claim 4 wherein the needle is treated by electro cleaning or electropolishing and the needle, when removed from the bath, is rinsed with water, dried and lubricated.
- 30 10. A method according to Claim 9 wherein the solution is maintained at a temperature of from about 110°C. to 130°C. and the needle is maintained in the solution for a period of time of at least 4 minutes.

FIG-3

SELECT A NEEDLE CONTAINING CHROMIUM AND HAVING A DESIRED SHAPE AND SHARPNESS (A)

TREAT SAID NEEDLE TO ACTIVATE THE SURFACE TO ALLOW THE CHROMIUM TO FORM OXIDES (B)

SUBMERSE THE NEEDLE IN A SOLUTION OF SULFURIC ACID, POTASSIUM DICHROMATE AND WATER (C)

MAINTAINING THE SOLUTION AT A TEMPERATURE OF AT LEAST 100°C (D)

MAINTAINING THE NEEDLE IN THE HEATED SOLUTION FOR A SUFFICIENT TIME TO DARKEN THE SURFACE OF THE NEEDLE (E)

REMOVE THE NEEDLE FROM THE SOLUTION (F)

RINSE THE NEEDLE (G)

DRY THE NEEDLE (H)

LUBRICATE THE NEEDLE (I)

ATTACH A SUTURE TO THE BLUNT END OF THE NEEDLE (J)

PLACE THE SUTURE AND NEEDLE IN AN APPROPRIATE PACKAGE (K)

STERILIZE THE PACKAGE CONTAINING THE NEEDLE AND SUTURE (L)

FIG-1

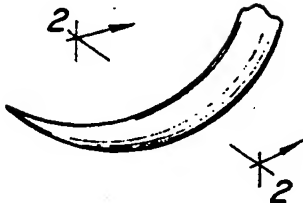


FIG-2





DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
A	FR-A-2 287 892 (LES LABORATOIRES BRUNEAU & CIE.) * Claim 1 *	1	A 61 B 17/06 C 23 C 22/24
A	CH-A- 322 486 (S. & R.J. EVERETT & CO. LTD.) * Claim 1 *	1	
A	EP-A-0 052 056 (NIPPON STEEL CORP.) * Claim 1 *	4	
A	US-A-3 210 220 (N.E. CLEGG et al.) * Claim 1; column 1, lines 66-68 *	4	
			TECHNICAL FIELDS SEARCHED (Int. Cl.4)
			A 61 B 17/00 C 23 C 22/00 D 05 B 85/00
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 27-09-1985	Examiner PAPA E.R.
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	